RFA-100 Tumor Radiofrequency Ablation System – Acute Animal (Porcine) Trial Report

Purpose of the Trial

This trial used pigs as the animal model to evaluate the precision and effectiveness of the RFA-100 Tumor Radiofrequency Ablation System.

This was an acute trial (dissection performed on the day of surgery) primarily aimed at assessing the ablation area and the state of ablated cells.

Trial Design

On the day of surgery, the animal was sedated and induced under anesthesia. After successful induction, oral visual endotracheal intubation was performed, and the animal was connected to a ventilator. The anesthetized and intubated animal was placed in the supine position on the operating table and secured with restraining straps. Using a high-frequency electrosurgical unit, the pig liver was exposed.

A RENE-10-2 radiofrequency ablation needle (suitable for tumors ⩽ 2 cm in diameter) was inserted into the pig liver to a depth of 4 cm, ensuring that no exposed electrode was visible and that it did not contact the neutral electrode. A temperature probe was placed parallel to the RFA needle, 1 cm apart, inserted into the liver to a depth of 3 cm. The neutral electrode and water cooling tube were connected, the peristaltic pump was activated to remove air from the water tube, and then the intelligent mode was started to simulate the ablation of a 2 cm diameter tumor.

After ablation was complete, the RENE-10-2 RFA needle and temperature probe were removed. The animal was then euthanized via injection.

The liver was cut along the needle tract to observe the ablation shape. A vernier caliper was used to measure the long and short diameters of the ablation area. HE-stained sections of the ablation area were prepared to observe the cell survival status.

Endpoints

Intraoperative evaluation:
Ablation efficiency: Record ablation time
Cutting/closure efficiency: The closure efficiency of the test group should be non-inferior to that of the control group
Adhesion, carbonization, charring odor, smoke, and device-related adverse events: Record intraoperative charring odor, smoke, and any device-related adverse events; record adhesion when removing the needle; record carbonization after cutting open the ablation area
Ablation area: Record the long and short diameters using a vernier caliper

Regulatory Compliance Statement

All procedures in this trial were conducted in accordance with the Regulations on the Administration of Laboratory Animals, the Guidelines for Ethical Review of Laboratory Animal Welfare, and the Guidelines for Animal Experiment Research Registration and Review for Medical Devices - *Part II: Trial Design and Implementation Quality Assurance*.

No deviations related to the above management standards or trial protocols occurred.

This report accurately reflects the original trial data, and no other adverse factors affected trial quality or data integrity.

Quality Assurance Statement

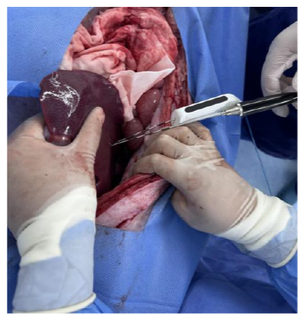
This research report has been reviewed by the Quality Assurance Department of ReinnoVet. The report accurately and fully describes the study methods, procedures, and observations, and the results fully reflect the original clinical research data.

Test Procedure

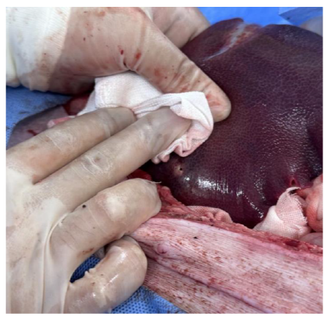
On the day of surgery, the animal was sedated and induced under anesthesia. After successful induction, oral visual endotracheal intubation was performed, and the animal was connected to a ventilator. The anesthetized and intubated animal was placed supine on the operating table and secured with straps. Using a high-frequency electrosurgical unit, the pig liver was exposed.

A RENE-10-2 RFA needle was inserted into the liver to a depth of 4 cm, ensuring no exposed electrode and no contact with the neutral electrode. A temperature probe was placed parallel to the RFA needle, 1 cm apart, inserted to a depth of 3 cm. The neutral electrode and water cooling tube were connected, the peristaltic pump was started to remove air, and the intelligent ablation mode was activated.

After 7 minutes of ablation, the system indicated completion and automatically ended the ablation process. The RENE-10-2 RFA needle and temperature probe were then removed. While still under anesthesia, the animal was euthanized by intravenous injection of 10% potassium chloride solution.



The RENE-10-2 radiofrequency ablation needle and the temperature probe are inserted into the liver in parallel



Ablation completed, remove the RENE-10-2 radiofrequency ablation needle and the temperature probe



Activate intelligent ablation mode

Results

(1) During ablation, no charring odor or smoke was observed, the device operated normally, and no adverse events occurred.

(2) After ablation, the RFA needle was removed smoothly with no adhesion.

(3) No significant carbonization was observed after cutting open the ablation area. The ablation zone was white and nearly spherical, with a long diameter of 20.74 mm and a short diameter of 20.08 mm.

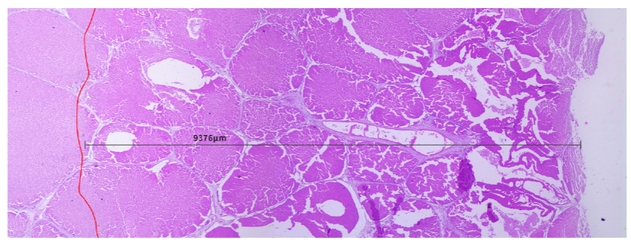


Ablation area long diameter: 20.74mm

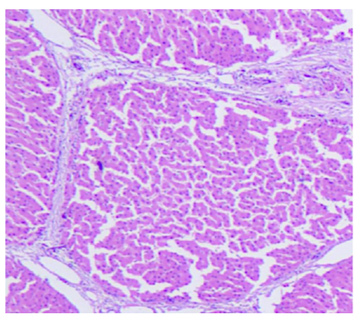


Ablation area short diameter: 20.08mm

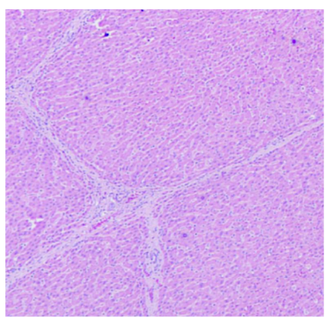
(4) Histological HE staining showed the ablation zone in a darker color with evident disintegration and fragmentation. Cells within the temperature field generated by the RF current were dehydrated and necrotic, with obvious gaps between dead cells and a disordered distribution. The distance from the ablation center to the outermost ablation boundary was 9,376 μm, equivalent to an ablation radius of 0.9376 cm from the needle tract.



The radius from the ablation center to the outermost ablation boundary is 9,376μm



Enlarged view of the ablation area: necrotic cells exhibit a disordered distribution pattern



Enlarged view of the non-ablated area: normal cells exhibit an orderly distribution pattern

Acute Animal Experiment Conclusion

(1) The RFA-100 Tumor Radiofrequency Ablation System, through impedance and temperature monitoring mechanisms combined with a feedback control algorithm, can achieve precise tumor ablation while minimizing over-ablation and damage to surrounding tissues.

(2) It demonstrates excellent surgical efficiency, completing the simulated ablation of a 2 cm tumor in only 7 minutes, with no smoke, carbonization, or adhesion during the procedure—significantly improving the efficiency of tumor treatment.

(3) The system is simple to operate, with no need for the physician to set power or ablation time before surgery.

(4) The ablation effect is precise and effective. Cells within the intended ablation range showed dehydration and death due to the temperature field generated by RF current, with a disordered and loose distribution pattern.